

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT EXAMINING OPERATION

First Named Inventor: PARTHASARADHI REDDY et al.

Serial No: 10/539,736

Group Art Unit: 1625

Filed: 06/20/2005

Examiner: RAHMANI, N.

Att. Docket No.: H1089/20025

Confirmation No.: 8607

For: NOVEL PROCESS FOR THE PREPARATION OF SIMVASTATIN

RESPONSE UNDER 37 CFR §§ 1.111 AND 1.143

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INTRODUCTORY COMMENTS

In response to the Office Action dated 03/29/2006, setting forth a requirement for restriction, and in accordance with the provision of 37 CFR 1.111 and 1.143, Applicants provisionally elect **with traverse**, Group I, claims 1-45, drawn to a process for the preparation of simvastatin of Formula I using a compound of Formula II.

Remarks/Arguments begin on page 2 of this paper.

REMARKS/ARGUMENTS

In the Office Action dated 03/29/2006, the Examiner has set forth a requirement for restriction pursuant to 35 USC 121 and 372, alleging that the subject matter defined by the claims is not so linked as to form a single general inventive concept under PCT Rule 13.1.

The Examiner has restricted the claims into three groups. The first group, claims 1-45, is drawn to a process for the preparation of simvastatin using a compound of formula II, the second group, claims 1-45, is drawn to a process for the preparation of simvastatin using a compound of formula III, and the third group, claims 46-65, is drawn to a compound selected from compounds with formula V, VI, VIIa or VIIb. In addition, the Examiner has set forth the requirement that if Group III is elected, Applicant must further choose one compound selected from the compound of formula V, VI, VIIa or VIIb.

PCT Rule 13.1 sets forth that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). PCT Rule 13.2 sets for that the expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant case, the special technical feature which links the claimed inventions is the novel process of producing simvastatin of formula I wherein the claimed method uses and produces novel intermediates which are not found in the prior art. Since the inventions are linked by this special technical feature they are a single inventive concept. In addition, this special technical feature defines an advance over the prior art because the claimed method is not taught in the prior art, nor are the

Application No. 10/539,736
Amendment Dated 4/28/2006
Reply to Office Action of 03/29/2006

intermediates taught in the prior art. The Examiner alleges that the instant invention is disclosed in U.S. Patent No 5,462,933, however, the '933 patent does not disclose the intermediates used and produced in the claimed method, nor does it teach the steps used in the claimed method. The '933 patent does not teach methods which produce compounds of Formula V, VI, VIIa or VIIb. Since these are novel intermediates, produced in a method not taught by the prior art, the claimed method is an advance over the prior art.

Since the special technical feature which links the inventions is a contribution over the prior art, the claims have unity of invention under PCT Rule 13.1, and thus the requirement for restriction should be withdrawn. Reconsideration of the restriction requirement is respectfully requested.

Applicant has provisionally elected **with traverse**, Group I, claims 1-45, drawn to a process for the preparation of simvastatin of Formula I using a compound of Formula II. Applicant believes that the foregoing is a full and complete response to the Office Action of record.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Application No. 10/539,736
Amendment Dated 4/28/2006
Reply to Office Action of 03/29/2006

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned agent at the telephone number listed below.

April 28, 2006

Please charge or credit our
Account No. 03-0075 as necessary
to effect entry and/or ensure
consideration of this submission.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

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